

NOV 03 2004

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703 872 9306

**Voice Number:****Sender:**

Edward R. Ergenzinger, Jr.

**Message:**

Re: Appl. No. 10/769,952, filed March 10, 2004

Attached please find the Response to the Office Action dated October 5, 2004.

Number of Pages: (including cover page)

4

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NOV 03 2004

Attorney's Docket No. 046562/274659

PATENT

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re:	Fraser <i>et al.</i>	Confirmation No.:	4482
Appl No.:	10/769,952	Group Art Unit:	1653
Filed:	March 10, 2004	Examiner:	Rooke, Agnes Beata
For:	METHODS FOR TREATING LOWER URINARY TRACT DISORDERS AND THE RELATED DISORDERS VULVODYNIA AND VULVAR VESTIBULITIS USING CAV2.2 SUBUNIT CALCIUM CHANNEL MODULATORS		

November 2, 2004

Mail Stop Amendment  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

## RESPONSE TO ELECTION OF SPECIES

This is in response to the Office Action dated October 5, 2004, in which the Examiner has required an election of species within each of claims 2, 12, 33, and 36, namely an election between disclosed species of urinary tract disorder, disclosed species of methods of administration and pharmaceutical formulations, disclosed species of Cav2.2 calcium channel modulator, and disclosed species of a second Cav2.2 calcium channel modulator. Applicant hereby elects the species "overactive bladder" within the group of urinary tract disorders in claim 2 without traverse; the species "orally" within the group of methods of administration with traverse; the species "Ziconotide" within the group of Cav2.2 calcium channel modulators with traverse; and the species "ω-conotoxin GVIA" within the group of second Cav2.2 calcium channel modulators without traverse. Applicant expressly reserves the right to file divisional applications or take such other appropriate measures deemed necessary to protect the inventions in the remaining species.

Applicants provisionally elect the species "orally" with traverse

Applicants hereby provisionally elect with traverse to prosecute the species "orally" within the group "methods of administration and pharmaceutical formulations." Although the Examiner has stated that claim 12 is generic to a plurality of disclosed patentably distinct species directed to methods of administration and pharmaceutical formulations, the species cited by the Examiner as forming this group are found in claims 14-28. Specifically, the species cited by the Examiner are orally, transmucosally, sublingually, buccally, intranasally, transurethrally, rectally, by inhalation, topically, transdermally, parenterally, intrathecally, vaginally, perivaginally, vaginal suppositories, creams, ointments, liquid formulations, pessaries, tampons, gels, pastes, foams, sprays, tablets,

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capsules, caplets, solutions, suspensions, syrups, granules, beads, powders and pellets. Applicants respectfully traverse this election.

Applicants respectfully submit that the methods of the present invention comprise the use of Cav2.2 subunit calcium channel modulators to treat lower urinary tract disorders. The invention resides not in the mode of administration but rather in the combination of compounds used in the treatment. Applicants point out that if the search and examination of an application can be made without serious burden, the Examiner must examine the application on the merits even though it includes claims that are independent or distinct inventions. MPEP §803. In the present case, the search of the Cav2.2 subunit calcium channel modulators will reveal any mode of administration. Accordingly, there would be no serious burden of search if an election of species were not set forth for the method of administration.

Applicants provisionally elect the species "Ziconotide" with traverse

Applicants hereby provisionally elect with traverse to prosecute species "I" of claim 33 (Ziconotide or a salt, enantiomer, analog, ester, amide, prodrug, active metabolite, or derivative thereof) and expressly reserve the right to file divisional applications or take such other appropriate measures deemed necessary to protect the inventions in the remaining claims. The Examiner has stated that claim 33 is generic to a plurality of disclosed patentably distinct species comprising Cav2.2 subunit calcium channel modulators. Applicants respectfully traverse this election as to subsections "b" and "I" of claim 33.

Applicants respectfully submit that Ziconotide (subsection "I" of claim 33) is a synthetic form of the naturally occurring compound  $\omega$ -conotoxin MVIIA (subsection "b" of claim 33). Valentino *et al.* (1993) *Proc. Natl. Acad. Sci. USA* 90: 7894-7897. Ziconotide is the man-made equivalent of  $\omega$ -conotoxin MVIIA and was developed due to the dangers and difficulties inherent in harvesting naturally occurring toxins from cone snails. Nelson *Nature* 429: 798-799 (2004). Because Ziconotide and  $\omega$ -conotoxin MVIIA share the same physical and physiological properties, Applicants respectfully submit that species "b" and "I" should be examined together.

As noted by the Examiner, it is understood that upon the allowance of a generic claim, Applicants will be entitled to consideration of claims to additional species that are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 C.F.R. §1.141. With respect to the election of "orally," claim 15 reads on claim 14. With

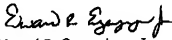
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Response to Election of Species

respect to the election of "Ziconotide or a salt, enantiomer, analog, ester, amide, prodrug, active metabolite, or derivative thereof," no current claims read on claim 33.

Should the Examiner have further questions or comments with respect to examination of this case, it is respectfully requested that the Examiner telephone the undersigned so that further examination of this application can be expedited.

It is not believed that extensions of time or fees for net addition of claims are required beyond those which may otherwise be provided for in documents accompanying this paper. However, in the event that additional extensions of time are necessary to allow consideration of this paper, such extensions are hereby petitioned under 37 CFR § 1.136(a), and any fee required therefore (including fees for net addition of claims) is hereby authorized to be charged to Deposit Account No. 16-0605.

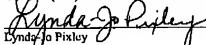
Respectfully submitted,

  
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I hereby certify that this paper is being facsimile transmitted to the US Patent and Trademark Office at  
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Lynda Jo Pixley

November 2, 2004  
Date